UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK -------x ZACHARY SOLOMON,

Plaintiff,

-against-

Case No. 20-cv-3213-FB-ST

MEMORANDUM AND ORDER

ST. JOSEPH HOSPITAL AND CATHOLIC HEALTH SYSTEM OF LONG ISLAND, INC.,

Defendants.

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Appearances:
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BLOCK, Senior District Judge:

Plaintiff Zachary Solomon ("Solomon") brings this action for medical malpractice, negligent hiring and supervision, and gross negligence against Defendants St. Joseph Hospital in Bethpage, New York ("St. Joseph") and Catholic Health System of Long Island, Inc., the owner of St. Joseph. Solomon was treated for COVID-19 at St. Joseph and during his stay developed an unstageable pressure ulcer that required multiple surgeries to remedy. All of Solomon's claims are based on state law. However, Defendants removed the case to federal court based on the PREP Act, a federal law that provides liability immunity under certain situations to health care providers administering treatment for COVID-19. They now move to dismiss for failure to state a claim upon which relief can be granted under Rule 12(b)(6) and lack of subject matter jurisdiction under Rule 12(b)(1). For the following reasons, Defendants' motions are denied.

I.

The following facts are taken from the complaint. For present purposes, the Court accepts them as true and draws all reasonable inferences in favor of the plaintiff. *See, e.g., Gamm v. Sanderson Farms, Inc.*, 944 F.3d 455, 458 (2d Cir. 2019).

On March 23, 2020, Solomon presented to the emergency department of St. Joseph. He was positive for COVID-19 and was admitted to the hospital due to

impending respiratory failure. Shortly thereafter, Solomon was intubated and placed on a ventilator. He remained on a ventilator for several days, recovered from COVID-19 and was ultimately discharged from St. Joseph on April 14, 2020.

During his hospital stay, Solomon developed an unstageable pressure ulcer. Pressure ulcers are graded I through IV, or, if so severe that they exceed stage IV, they are termed "unstageable." Upon Solomon's discharge, agents of St. Joseph advised him that his pressure ulcer was Stage II, when it was in fact unstageable. In addition, during Solomon's stay at St. Joseph, agents of the hospital informed Solomon's family that he was being properly rotated on a regular basis to avoid a pressure injury. However, Solomon was not being consistently rotated and was not rotated at all for up to six days, resulting in the development of the pressure injury. After discharge, Solomon underwent multiple surgeries to treat his pressure ulcer.

Defendants presently challenge Solomon's complaint on the bases of immunity to liability and lack of jurisdiction under the federal Public Readiness and Emergency Preparedness Act ("PREP Act") and New York's Emergency Disaster Treatment Protection Act ("EDTPA").

II.

A case will be "dismissed for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1) when the court lacks the statutory or constitutional power to adjudicate it." *Makarova v. U.S.*, 201 F. 3d 110, 113 (2d

Cir. 2000). In resolving a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), the court may refer to evidence outside the pleadings. *See Kamen v. American Tel. & Tel. Co.*, 791 F. 2d 1006, 1011 (2d Cir. 1986). "A plaintiff asserting subject matter jurisdiction has the burden of proving by a preponderance of the evidence that it exists." *Makarova v. U.S.*, 201 F. 3d 110, 113 (2d Cir. 2000).

III.

Defendants argue that the PREP Act preempts the claims made in the instant suit, therefore depriving this Court of jurisdiction under Rule 12(b)(1).

The PREP Act provides liability protections to "covered person[s]" with respect to all claims that arise out of, relate to, or result from "the administration to or the use by an individual of a covered countermeasure if a Declaration under subsection (b) has been issued with respect to such countermeasure." 42 U.S.C.A. § 247d-6d(a)(1). This declaration must be made by the Secretary of the United States Department of Health and Human Services ("the Secretary") in order to activate the law if he or she "makes a determination that a disease [...] constitutes a public health emergency." 42 U.S.C.A. § 247d-6d(b)(1). On March 17, 2020, the Secretary issued this declaration invoking the PREP Act for the COVID-19 public health emergency. The scope of liability immunity is limited to claims for losses

that have a "causal relationship with the administration to or use by an individual of a covered countermeasure." 42 U.S.C.A. § 247d-6d(a)(2)(B).

The Secretary's March 2020 Declaration defines a "covered countermeasure" as

any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

85 Fed. Reg. 15, 198 (Mar. 17, 2020). There have been eight amendments to the March 2020 Declaration issued by the Secretary, the first of which included "respiratory protective devices" as covered countermeasures. 42 U.S.C.A. § 247d-6d(i)(1)(D); Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 21012-02, at 21013-14 (April 15, 2020). In December 2020, the Declaration was again amended, further expanding the definition of a covered countermeasure as

Any antiviral, any drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine manufactured, used, designed, developed, modified, licensed, or procured: (i) [t]o diagnose, mitigate, prevent, treat, or cure COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom; or (ii) to limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause [...]

Amendment to Declaration Under the Public Readiness and Emergency

Preparedness Act for Medical Countermeasures Against COVID-19, 85 FR 79,

196 (Dec. 3, 2020). In Solomon's case, a ventilator was a device used to treat

COVID-19 and is therefore a covered countermeasure under the PREP Act. This is undisputed by the parties.

Defendants argue that Solomon's claim derives from his treatment with a ventilator, or covered countermeasure, and that therefore his claim is preempted by the PREP Act. Regarding preemption, the PREP Act provides, in relevant part:

During the effective period of a declaration under subsection (B), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure and provision of law or legal requirement that – (A) is different from, or is in conflict with, any requirement applicable under this section; and (B) relates to the use [...] or administration by qualified persons of the covered countermeasure.

42 U.S.C.A. § 247d-6d(b)(8). In the context of COVID-19, a number of federal district courts have found that the PREP Act does not preempt state law medical malpractice and negligence claims when the claims arise from issues of alleged duty and "proper standards of general medical [...] care, not the administration or use of certain drugs, biological products, or devices, *i.e.*, the countermeasures covered under the PREP Act." *Dupervil v. Alliance Health Operations*, 516 F. Supp. 3d 238, 257 (E.D.N.Y. 2021); *see also, e.g., Estate of Jones through Brown*

v. St. Jude Operating Co., LLC, 2021 WL 886217 (D. Or.); Estate of Maglioli v. Andover Subacute Rehabilitation Center I, 478 F. Supp. 3d 518 (D.N.J. 2020); Lyons v. Cucumber Holdings, LLC, et al., 2021 WL 364640 (C.D. Cal.). To be covered under the PREP Act, there must be "a causal connection between the injury and the use or administration of covered countermeasures." Dupervil at 256 (quoting Brown v. Big Blue Healthcare, Inc., 480 F. Supp. 3d 1196, 1205-06 (D. Kan. 2020)). Solomon's claims, therefore, hinge on whether his injury results from the use of a ventilator to treat his COVID-19 infection, or rather from the hospital's alleged failure to uphold a duty and proper standards of medical care separate from the use of the ventilator.

It is apparent from the parties' submissions that Solomon's claims derive from a common type of hospital-acquired injury that results from not being rotated while stationary. Therefore, the claims arise from issues of alleged failure to uphold a duty and proper standards of medical care, rather than directly from the use of a ventilator or covered countermeasure. While Solomon was indisputably being treated for COVID-19 with a ventilator during the period that he acquired a pressure injury, the claims he has brought are not so inextricably intertwined with the use of a covered countermeasure so as to invoke PREP Act preemption at this stage. *See Dupervil* at 256. The Court finds that Solomon has sufficiently pleaded for the purposes of this motion that his injuries resulted from a cause separate from

a covered countermeasure.¹ Therefore, the Court is not deprived of the statutory or constitutional power to adjudicate this case, and Defendants' motion to dismiss for lack of subject matter jurisdiction is denied.

IV.

"To survive a motion to dismiss [under Rule of 12(b)(6)], a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). The pleading must offer more than "bare assertions," "conclusory" allegations, or a "formulaic recitation of the elements of a cause of action." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

A complaint is "deemed to include any written instrument attached to it as an exhibit, materials incorporated in it by reference, and documents that, although

¹ At oral argument, Defendants argued that overcoming PREP Act immunity requires willful misconduct. This is true when the injury in question results from the use of a covered countermeasure. *See* 42 U.S.C.A. § 247d-6d(d)(1). Because Solomon has alleged that his injury resulted from a cause other than the use of a covered countermeasure, he need not show willful misconduct to escape PREP Act immunity. Regardless, Solomon has alleged willful misconduct. *See infra* page 11 for a description of the intentional wrongdoing that Solomon alleges.

not incorporated by reference, are 'integral' to the complaint." Sierra Club v. Con-Strux, LLC, 911 F.3d 85, 88 (2d Cir. 2018) (quoting Sira v. Morton, 380 F.3d 57, 67 (2d Cir. 2004)).

V.

Defendants' Rule 12(b)(6) motion is based on a defense of liability immunity granted to health care providers during the COVID-19 crisis under A) the PREP Act and B) New York's EDTPA.

A. PREP Act Immunity

For the reasons described above, the Court finds that Solomon has sufficiently pleaded that his injury does not derive from the use of a covered countermeasure, as required to invoke PREP Act immunity. *See* 42 U.S.C.A. § 247d-6d(a)(1), (b)(8). Therefore, Defendants are not entitled to dismissal under Rule 12(b)(6) on the basis of the PREP Act.

B. EDTPA Immunity²

In addition to citing the PREP Act as a basis for immunity, Defendants argue that they are entitled to 12(b)(6) dismissal under the EDTPA. The purpose of the

² The EDTPA is a New York state law. Since the Court has federal jurisdiction, it will also address Defendants' state law immunity argument. *See* 28 U.S.C. § 1367.

EDTPA, similar to the PREP Act, is to provide immunity from liability to health care providers in New York who were treating patients for COVID-19 during the early days of the pandemic. See N.Y. Pub. Health Law § 3082. Though the EDTPA has been repealed in large part, its application holds for the period during which Solomon's injury was incurred. While conceptually the same as the PREP Act, the EDTPA affords broader liability immunity to health care providers treating patients for COVID-19. Specifically, health care providers are immune from claims that result from decisions or activities they make in response to the COVID-19 pandemic that impact a patient's treatment. See N.Y. Public Health Law § 3082(1)(a)-(b). Unlike the PREP Act, the EDTPA does not require the use of a covered countermeasure to afford health care providers liability immunity. In addition, the EDTPA does not afford immunity to providers who commit gross negligence. *Id* at (2).

Decisions interpreting the EDTPA's application are scarce. In *Townshend v. Penus, R.N., et al*, a New York State Supreme Court found that the defendants' motion to dismiss based on EDTPA immunity failed because it did not sufficiently demonstrate a nexus between the health care provider's decisions or activities in response to the COVID-19 crisis and the treatment of the plaintiff. *See Townshend*, Index No. 800321/2021E (Sup. Ct. Bronx Co. June 1, 2021). Although the *Townshend* decision is not binding on the Court, its reasoning is persuasive.

Solomon's treatment with a ventilator was undoubtedly a result of a health care provider's decision in response to the COVID-19 emergency. However, Defendants have not shown for the purposes of this motion that Solomon's pressure injury directly resulted from decisions or activities in response to or as a result of the COVID-19 outbreak. *See id.; see also* N.Y. Pub. Health Law § 3082(1). In addition, one of Solomon's allegations, that he was improperly informed of the severity of his pressure ulcer, occurred upon his discharge and after his treatment for COVID-19 had concluded. At this stage of the case, the Court finds that the EDTPA's immunity provision does not prevent plaintiff from proceeding with his claim.

Solomon also has sufficiently pleaded gross negligence. Gross negligence is "conduct that evinces a reckless disregard for the rights of others or 'smacks' of intentional wrongdoing." *American Tel. & Tel. Co. v. City of New York*, 83 F. 3d 549, 556 (2d Cir. 1996) (*quoting Colnaghi, U.S.A., Ltd. V. Jewelers Protection Servs., Ltd.*, 81 N.Y. 2d 821, 823-24 (1993)). Solomon's complaint alleges that Defendants deliberately misinformed Solomon and his family that he was being rotated on a regular basis to avoid a pressure injury when he in fact was not being rotated, and that he was misinformed of the severity of his injury. These assertions satisfy Solomon's burden at this stage of the case to allege intentional wrongdoing on the Defendants' part. Therefore, Solomon's gross negligence claim also

survives Defendants' motion to dismiss based on the EDTPA's exception for gross negligence. *See* N.Y. Public Health Law § 3082(2).

CONCLUSION

Defendants' motion to dismiss is **DENIED** for the reasons described above. **SO ORDERED.**

/S/ Frederic Block
FREDERIC BLOCK
Senior United States District Judge

Brooklyn, New York September 29, 2021